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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,317	03/28/2001	Patrick L. Coleman	56066USA1A.002	4377

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Attention: Christopher D. Gram
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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 10/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/819,317

Applicant(s)

COLEMAN ET AL.

Examiner

Jeffrey Fredman

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-15,23 and 26 is/are pending in the application.
- 4a) Of the above claim(s) 12-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-11,23 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3-11, 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halverson et al (WO 99/53319) in view of Kreisher et al (U.S. Patent 4,589,965).

Halverson teaches a method of transferring molecules to a laminate (see page 6, lines 12-17) comprising:

(a) providing a laminate (see page 3) comprising

i) a shrinkable polymeric substrate having a projected surface area and a topographical surface area (see page 3, lines 7-16)

ii) a hydrogel disposed on at least a portion of the substrate (see page 8, lines 9-18, page 9, lines 8-35 and page 10, lines 5-9),

(b) contacting the laminate with the molecules to be affixed (see page 6, lines 12-17 and page 17, lines 19-35)

(c) transferring said molecules to the laminate (see page 17, lines 19-35)

(d) removing the laminate from the transfer process (see page 17, lines 19-35)

Art Unit: 1637

(e) shrinking the laminate so that the topographical surface area is greater than the projected surface area (see page 3, lines 7-31, page 11, lines 16-22, page 37, claims 8-10).

Halverson teaches the use of azlactone copolymers (see page 12, line 33-35). Halverson further teaches the use of a masking layer (see page 13, lines 30-33) as well as coating nucleic acids, amino acids and proteins onto the laminate (see page 7, lines 12-15). Halverson further teaches detection of the molecules transferred onto the laminate (see example 17, pages 33-35). Halverson further teaches the use of covalently bonded linkage moieties (see page 6, line 13).

Halverson does not teach transfer of the molecules using a matrix to the laminate.

Kreisher et al (U.S. Patent 4,589,965) teaches electroblot transfer of molecules from a matrix to an immobilizing material (see column 2, lines 3-67). In particular, Kreisher teaches the steps of

(b) contacting the matrix with the immobilizing material (see column 2, lines 35-43)

(c) transferring the molecules from the matrix to the immobilizing material (see column 2, lines 55-60)

(d) removing the matrix from the immobilizing material (column 5, lines 61-62).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to transfer the molecules onto the laminates of Halverson using the electroblot method of Kreisher since Halverson expressly states "Affix' shall

Art Unit: 1637

include any mode of attaching reactants to a substrate. Such modes shall include, without limitation, covalent and ionic binding, adherence, such as with an adhesive, and physical entrapment within a substrate (page 6, lines 12-14)". An ordinary practitioner, faced with the express suggestion of Halverson to "affix" the molecules by any desirable method, would have been motivated to select the method of Kreisher since Kreisher states "Therefore it is a principal advantage of the present invention to provide a rapid and efficient method for electroblotting (see column 2, lines 19-21)." Kreisher continues a sentence later to note "It is an additional object of the present invention to provide a method as aforesaid which obtains high resolution and absence of diffusion (see column 2, lines 25-27)." An ordinary practitioner would have been motivated to follow the express suggestion of Halverson to affix the molecules using multiple modes and to utilize the mode of Kreisher since Kreisher indicates that the electroblotting method is fast, it is efficient and it has high resolution, all characteristics desirable to Halverson, in particular the high resolution.

Response to Arguments

3. Applicant's arguments filed September 16, 2002 have been fully considered but they are not persuasive.

The 102 rejection is withdrawn in view of the amendment, and the arguments are consequently moot with regard to this rejection.

The 103 rejection is modified to directly address the amended claims, but is maintained.

Art Unit: 1637

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, specific motivation is provided in the rejection. However, the best motivation is provided in the Halvorsen reference, which suggests that any mode of affixing the molecules is desired.

4. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant then argues this is an obvious to try situation with no reasonable expectation of success. The legal standard for "reasonable expectation of success" is provided by caselaw and is summarized in MPEP 2144.08, which notes "obviousness does not require absolute predictability, only a reasonable expectation of success; i.e., a reasonable expectation of obtaining similar properties. See, e.g., *In re O'Farrell*,

Art Unit: 1637

853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).” In this factual case, there is express suggestion in the prior art of Kreisher that molecules can be transferred by electrophoretic means from one support to another support. This sufficient for a reasonable expectation of success. The MPEP cites *In re O’Farrell*, which notes regarding “obvious to try” at page 1682, that,

“In some cases, what would have been “obvious to try” would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. E.g., *In re Geiger*, 815 F.2d at 688, 2 USPQ2d at 1278; *Novo Industri A/S v. Travenol Laboratories, Inc.*, 677 F.2d 1202, 1208, 215 USPQ 412, 417 (7th Cir. 1982); *In re Yates*, 663 F.2d 1054, 1057, 211 USPQ 1149, 1151 (CCPA 1981); *In re Antonie*, 559 F.2d at 621, 195 USPQ at 8-9. In others, what was “obvious to try” was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. *In re Dow Chemical Co.*, 837 F.2d, 469, 473, 5 USPQ2d 1529, 1532 (Fed. Cir. 1985); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380, 231 USPQ 81, 90-91 (Fed. Cir. 1986), cert. denied, 107 S.Ct. 1606 (1987); *In re Tomlinson*, 363 F.2d 928, 931, 150 USPQ 623, 626 (CCPA 1966).

The court in *O’Farrell* then, affirming the rejection, notes “ Neither of these situations applies here.” For the instant case, it is clear that neither situations applies here either. This is not a situation where the prior art suggests varying a variety of parameters, since the prior art of Kreisher directly points to the use of electroblotting as a means of transferring molecules from one support to another. This is also not a situation where

only general guidance was given. The prior art provides specific guidance directing the use of electroblotting and Halversen expressly suggests that any known means of affixing is desirable (see column 6) and Kreisher provides a known means of affixing as discussed in the rejection. Applicant's argument that a coating might have interfered with the transfer does not overcome Halverson's teaching of an expectation of success since Halveron expressly indicates that any mode of affixing would be expected to function (see column 6).

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

Art Unit: 1637

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman
Primary Examiner
Art Unit 1637

October 29, 2002